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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,520	04/21/2008	Theresa M. Reineke	91830.0542769	7539

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EXAMINER	
SCHULTZ, JAMES	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
12/21/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,520	REINEKE ET AL.	
	Examiner	Art Unit	
	James (Doug) Schultz, PhD	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-17 and 19-32* is/are pending in the application.

4a) Of the above claim(s) *16,19-22,24,25,28,29 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-15,-17,23,26,27,30 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 4, claims 11-17 and 19-32, in the reply filed on June 17, 2010, and the election of the species "polyhydroxylamidoamines" in the reply filed on September 30, 2010 is acknowledged.

Applicant's election with traverse of reperfusion disorder in ischemic disease in the reply filed on June 17, 2010 is acknowledged. The traversal is on the ground(s) that the amendment of June 17, 2010 provides to the claims a technical feature (a polymeric vector) that Morishita does not teach, and that the instant claim set is thus distinguished over the prior art. This is not found persuasive because as cited below, the amended claims are not considered free of the prior art. Upon notice of allowable subject matter, rejoinder will occur in regards to those inventions that fall within the scope of the allowed subject matter.

Applicants have argued that the election of "reperfusion disorder in ischemic disease" should be examined with regard to claims 17, 23, 26, and 27, in addition to 11-15, since claims 17 and 23 recite "reperfusion injuries after ischemia", and since claims 26 and 27 recite "ischemic-reperfused myocardium" and "ischemic-reperfused brain," respectively. Applicants suggest that a search of those key words would likely return the same prior art references as the elected physiological condition, and thus would not present an undue additional search burden on the Examiner. While 35 U.S.C. 371 does not provide for a consideration of search burden when determining lack of unity, these species are rejoined since all of claimed conditions derive from ischemia and it's likely that a search for one may reveal art on another. Applicants traverse of

Morishita is not convincing for reasons provided above, and this aspect of the restriction is made final. Claims 11-15, 17, 23, 26, 27, and new claims 30 and 31 are examined, and claims 16, 19-22, 24, 25, 28, 29, and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 30, 2010.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The disclosure contains sequences which fall under the purview of 37 CFR 1.821 through 1.825 as requiring SEQ ID NOS:, but which are not so identified. For example, at least page 128 of the instant specification, several nucleotide sequences in excess of 10 nucleotides long are disclosed, and not identified by a SEQ ID NO:. Applicants should be aware that these sequences may not be the only instances necessitating this notice. Applicants should carefully review the application for any further examples of failures to identify any sequences by SEQ ID NO:, and to otherwise verify that the application is in compliance.

Applicant is required to comply with all sequence rules set forth in 37 CFR 1.821 through 1.825 in the next substantive response. This requirement will not be held in abeyance, and failure

to comply with these requirements may result in ABANDONMENT of the application under 37 CFR 1.821(g). Direct the reply to the undersigned. Please note that any sequences not already disclosed in the CRF will require amendment and resubmission of the CRF and the sequence listing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-15, 17, 23, 26 and, 27 are rejected under 35 U.S.C. 102(b) and as being anticiapated by Morishita et al. (U. S. Patent Number 6,262,033).

The invention is drawn to methods for treating NF-κB associated diseases comprising administering to an animal an NF-κB decoy wherein the decoy is delivered by a polymeric vector. The disease may be an ischemic disease, or reperfusion injuries or disorders in ischemic disease, or may treat heart (myocardium) or brain.

Morishita et al. teach treating NF-κB-associated diseases, including ischemic disease. The ischemic disease includes ischemic diseases of organs (e.g. ischemic heart diseases such as myocardial infarction, acute heart failure, chronic heart failure, etc., ischemic brain diseases such as cerebral infarction, and ischemic lung diseases such as pulmonary infarction), and reperfusion disorders. Morishita emphasizes that their pharmaceutical compositions containing the NF-κB decoy or well suited for the therapy and prophylaxis of reperfusion disorders in ischemic

diseases and post-PTCA restenosis, among other conditions. Morishita also teaches pharmaceutical compositions may be provided in liquid dosage forms such as solutions, suspensions, syrups, liposomes, lotions, etc. or in solid dosage forms such as tablets, granules, powders, and capsules, in vehicles, excipients, stabilizers, lubricants, and/or may containother conventional pharmaceutical additives, such as lactose, citric acid, tartaric acid, stearic acid, magnesium stearate, terra alba, sucrose, corn starch, talc, gelatin, agar, pectin, peanut oil, olive oil, caccao butter, ethylene glycol, and so on. Since the term "polymeric" is broadly defined, it is considered to include any type of polymer such as those found in liposomes (e.g. a carbon chain polymer that comprises fatty acids found in liposomes), or gelatins, or ethylene glycol, etc. in the lack of evidence to the contrary.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-15, 17, 23, 26, 27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reineke et al. (PMSE Preprints, Sept. 2003. 89:53-54), in view of Morishita et al. (U. S. Patent Number 6,262,033).

The invention is drawn to that as discussed above. Morishita does not teach that the polymeric vector is a polyhydroxylamidoamine.

Reineke et al. teaches polyhydroxylamidoamines identical to those disclosed for use in delivering therapeutic DNA compositions.

One of ordinary skill in the art would have been motivated to use the polyhydroxylamidoamine polymers of Reineke as a delivery aid in administering the decoys of Morishita. Morishita teaches the need for delivery compositions comprising their decoy, and lists numerous examples of such compositions including polymeric delivery vehicles as discussed in the rejection under 35 U.S.C. § 102(b). Reineke et al. teaches specific polyhydroxylamidoamine compounds identical to those disclosed and embraced by the instant claims, and teaches that such compounds show promise as gene and DNA delivery agents. One of ordinary skill would have considered the compounds of Reineke to be useful in delivering the decoy oligos of Morishita, and would have been motivated to do so given the widely acknowledged practice of employing delivery compounds when administering therapeutic DNA. Accordingly, one of ordinary skill in the art would have considered the invention to have been prima facie obvious at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-15, 17, 23, 26, 27, 30 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9,11,12,16-20,22-26,28,29,57-65 and 70-74 of copending Application No. 10/596,522. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the competing application are directed to kits comprising polyhydroxylamidoamines compounds that are identical to those claimed for use in the instant method, for the purpose of delivering therapeutic DNA, which the specification discloses includes NF-κB decoys. The claims are considered indistinct therefore.

This is NOT a provisional obviousness-type double patenting rejection because the conflicting claims have been allowed, though not in fact patented as of this writing.

Claims 11-15, 17, 23, 26, 27, 30 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 12/134556. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the competing application are drawn to polyhydroxylamidoamines for use in DNA delivery towards the treatment of disease, as are the instant claims. The competing specification contemplates the specific delivery of NF-κB decoys using such compounds. The claims are thus considered patentably indistinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-15, 17, 23, 26, 27, 30 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 and 19-29 of copending Application No. 10/596,516. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the competing application have identical scope, with two exceptions. First, the competing claims do not recite delivery methods that utilize specific polymers. However, the specification discloses that polymers identical to those claimed instantly can be used to enhance delivery. Second, the NF-κB decoy of the competing claims requires concatemerization, whereas the instant claims do not. However,

the instant claims use open language which embraces concatemerized decoys. Thus, neither of these differences render any patentable distinction between the claim sets.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James (Doug) Schultz, PhD whose telephone number is (571)272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James (Doug) Schultz, PhD/
Primary Examiner, Art Unit 1633